

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Volker NIER et al.

Serial No.: New

Filing Date: December 26, 2001

For: A METHOD FOR DETERMINING CONCENTRATION; A DIALYSER

PRELIMINARY AMENDMENT

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Prior to initial examination, please amend the above-identified application as follows:

IN THE CLAIMS

Please amend claims 4, 12-19, 23, 25, 26, 28 & 30 as follows:

4. A method in accordance with claim 1, wherein it is a question of a method for determining the ion concentration of blood of a patient in haemo-dialysis and/or haemo-filtration anti-coagulated with citrate, with the ion concentration of the blood being determined on the basis of the determination of the ion concentration in the dialysate and with the complexing of the relevant ion with citrate being prevented before the determination of the ion concentration in the dialysate for the purpose of determining the concentration.

12. A method in accordance with claim 6, wherein the setting of the pH in the dialysate takes place by means of an infusion of acid.

13. A method in accordance with claim 4, wherein the dialysate

flow is reduced for the purpose of approximating the ion concentration of the dialysate to the ion concentration of the blood.

14. A method in accordance with claim 4, wherein the determination of the ion concentration of the blood takes place by calculation without reducing the dialysate flow.

15. A method in accordance with claim 4, wherein the detection of the ion concentration in the dialysate takes place by means of an ion-sensitive sensor in the dialysate flowing away from the dialyser.

16. A method in accordance with claim 4, wherein the determined ion concentration of the blood of a patient serves as a controlled variable whose value is influenced by the control variables of citrate addition and/or addition of a substitution medium containing ions.

17. A method in accordance with claim 4, wherein an alarm is triggered when the determined ion concentration in the blood of the patient lies outside a permitted range or differs from a permitted value.

18. A method in accordance with claim 4, wherein the ion concentration in the compartment of the dialyser on the blood side is determined without interrupting the citrate supply and is compared with a permitted threshold value of the ion concentration and the citrate feed is changed in dependence on this comparison.

19. A method in accordance with claim 4, wherein the ions are calcium ions and/or magnesium ions.

23. A dialyser in accordance with claim 20, wherein means for adding a substance are connected to the dialysis line by which the pH of the dialysate can be changed.

25. A dialyser in accordance with claim 20, wherein means are provided by which the dialysate flow can be reduced temporarily.

26. A dialyser in accordance with claim 20, wherein a control unit is provided which controls the means for adding citrate to the blood in time intervals or on actuation by the operator such that the addition is temporarily interrupted and which records the concentration value determined by the means for detecting an ion concentration in the dialysate after the start of the interruption of the citrate addition continuously or in time intervals.

28. A dialyser in accordance with claim 20, wherein a regulating unit is provided which is connected to the means for detecting an ion concentration in the dialysate and to the means for adding citrate and/or to the means for adding a substitution solution containing ions and which initiates an increase or a lowering of the addition amount of citrate and/or of substitution solution containing ions in dependence on the comparison between a nominal value or a nominal value range and the determined actual value of the ion concentration.

30. A dialyser in accordance with claim 20, wherein an alarm unit is provided which triggers an alarm on determination of a critical

individual measurement of the ion concentration or on determination of a critical trend of individual measurements.

Please cancel claim 27 without prejudice or disclaimer.

**REMARKS**

The foregoing Preliminary Amendment is requested in order to delete the multiple dependent claims and avoid paying the multiple dependent claims fee and to cancel claim 27.

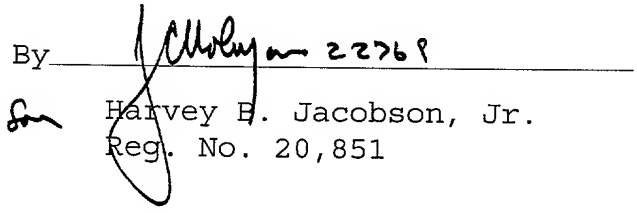
Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Early action on the merits is respectfully requested.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

4. A method in accordance with claim 1 [any of claims 1 to 3], wherein it is a question of a method for determining the ion concentration of blood of a patient in haemo-dialysis and/or haemo-filtration anti-coagulated with citrate, with the ion concentration of the blood being determined on the basis of the determination of the ion concentration in the dialysate and with the complexing of the relevant ion with citrate being prevented before the determination of the ion concentration in the dialysate for the purpose of determining the concentration.

12. A method in accordance with claim 6 [either of claims 6 or 11], wherein the setting of the pH in the dialysate takes place by means of an infusion of acid.

13. A method in accordance with claim 4 [any of claims 4 to 12], wherein the dialysate flow is reduced for the purpose of approximating the ion concentration of the dialysate to the ion concentration of the blood.

14. A method in accordance with claim 4 [any of claims 4 to 13], wherein the determination of the ion concentration of the blood takes place by calculation without reducing the dialysate flow.

15. A method in accordance with claim 4 [any of claims 4 to 14], wherein the detection of the ion concentration in the dialysate takes place by means of an ion-sensitive sensor in the dialysate

flowing away from the dialyser.

16. A method in accordance with claim 4 [any of claims 4 to 15], wherein the determined ion concentration of the blood of a patient serves as a controlled variable whose value is influenced by the control variables of citrate addition and/or addition of a substitution medium containing ions.

17. A method in accordance with claim 4 [any of claims 4 to 16], wherein an alarm is triggered when the determined ion concentration in the blood of the patient lies outside a permitted range or differs from a permitted value.

18. A method in accordance with claim 4 [any of claims 4 to 17], wherein the ion concentration in the compartment of the dialyser on the blood side is determined without interrupting the citrate supply and is compared with a permitted threshold value of the ion concentration and the citrate feed is changed in dependence on this comparison.

19. A method in accordance with claim 4 [any of claims 4 to 18], wherein the ions are calcium ions and/or magnesium ions.

23. A dialyser in accordance with claim 20 [any of claims 20 to 22], wherein means for adding a substance are connected to the dialysis line by which the pH of the dialysate can be changed.

25. A dialyser in accordance with claim 20 [any of claims 20 to 24], wherein means are provided by which the dialysate flow can be reduced temporarily.

26. A dialyser in accordance with claim 20 [any of claims 20 to

25], wherein a control unit is provided which controls the means for adding citrate to the blood in time intervals or on actuation by the operator such that the addition is temporarily interrupted and which records the concentration value determined by the means for detecting an ion concentration in the dialysate after the start of the interruption of the citrate addition continuously or in time intervals.

28. A dialyser in accordance with claim 20 [any of claims 20 to 27], wherein a regulating unit is provided which is connected to the means for detecting an ion concentration in the dialysate and to the means for adding citrate and/or to the means for adding a substitution solution containing ions and which initiates an increase or a lowering of the addition amount of citrate and/or of substitution solution containing ions in dependence on the comparison between a nominal value or a nominal value range and the determined actual value of the ion concentration.

30. A dialyser in accordance with claim 20 [any of claims 20 to 29], wherein an alarm unit is provided which triggers an alarm on determination of a critical individual measurement of the ion concentration or on determination of a critical trend of individual measurements.